REMARKS

Claims 1 and 4-22 currently appear in this application. The Office Action of November 30, 2007, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicant respectfully requests favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Claim Amendments

Claims 1, 18 and 19 have been amended to incorporate the limitation from claim 2 of "having a concentration of 100 mM or less." Although the specification did not use these exact words, the fact that claim 2 originally recited a range of from 0 to 100 mM would include concentrations of 100 mM or less. It would be readily understood by one skilled in the art that a concentration of 0 mM would not be possible if the sample is made into an aqueous solution.

Claim 18 has been amended to incorporate specific pH ranges. Support for this amendment can be found in the specification as filed at page 15, line 19; page 16, line 18 and page 17, line 5.

Claims 2 and 3 are cancelled.

The Claimed Invention

The herein claimed invention is based upon a new finding that impurities such as DNA contaminants and viruses are separated as particles from an aqueous solution of a physiologically active protein-containing sample when the pH and the concentration of the solution are adjusted to a pH equal to or lower than the isoelectric point of the protein and a concentration of 100 mM or less, respectively. Therefore, satisfying each of the limitations is critical to the presently claimed method so that impurities such as DNA contaminants and viruses can be effectively removed from the sample without the need to use a complicated process such as a chromatographic treatment.

Election/Restriction

It is noted that the election requirement has been made final.

Rejections under 35 U.S.C. 112

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As the present amendment cancels claims 2 and 3, this rejection is now moot.

Art Rejections

Claims 1, 2, 7, 8, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Faupel et al., U.S. 4,971,670.

This rejection is respectfully traversed. The aqueous solution in the claimed method must have a molarity of 100 mM or less, or an ionic strength of 0 to 0.2, as stated in the specification as filed at page 14, lines 6-12. This concentration of the aqueous solution is critical to the presently claimed method. There is no such disclosure of concentration of the solution in Faupel.

In addition, Faupel relates to a separation or purification method of a neutral chemical compound by using an isoelectric focusing electrophoretic process. However, there is neither teaching nor suggestion in Faupel of a method for removing impurities such as DNA contaminants and viruses as particles from a solution by adjusting the pH and the concentration of the solution to obtain particles of the contaminants, as claimed herein.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faupel in view of Naveh et al., EP 0 313 343.

This rejection is respectfully traversed. The Examiner admits that Faupel does not specifically indicate

that the solution has a morality [molarity?] between 0-100 mM, that the conductivity of the aqueous solution is between 0 and 300 mS/m or that the aqueous solution is selected from HCl, citric acid, or acetic acid. The Examiner states that Naveh teaches a method of purification wherein the solution has a molarity between 0 and 100 mM, that the conductivity of the aqueous solution is between 0-300 mS/m and that the aqueous solution is acidic.

This rejection is respectfully traversed. The teachings of Naveh on which the Examiner relies have nothing to do with the method claimed herein. Column 7, line 4, which teaches 0.01 M acetic acid, has nothing to do with the concentration of the protein being purified. In Naveh, this is the concentration of the acid in solution, not the concentration of the protein being purified. The concentration of the fraction to be purified, GM-CSF, is not disclosed.

The concentration of 100 mM or less in the presently claimed method is the concentration of the protein-containing solution. The concentration of the protein-containing solution is one important component of the clamed method.

The conductivity of Naveh is 13 ms/**cm**, which is equivalent to 1300 mS/m, which is more than an order of magnitude greater than the 300 mS/m claimed herein.

Furthermore, there is nothing in Naveh that teaches or suggests that particles of impurities such as DNA contaminants and viruses can be formed in a protein-containing solution by adjusting the pH and concentration of the solution, and that purification of the solution can be easily accomplished by removal of the particles therefrom. Naveh relates to ion-exchange chromatography, not to forming particles of impurities for subsequent removal.

Claims 1, 9, 10, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faupel in view of Vendantham et al., U.S. Published Application 2003/166869.

This rejection is respectfully traversed. The Examiner appears to admit that Faupel does not disclose that DNA contaminants are removed, that the product to be purified is an antibody, or that affinity chromatography is used in the disclosed method. Vendantham discloses a method for purifying proteins such as DNA contaminants, but the method used is hydroxyapatite chromatography, which has nothing to do with the particle-forming process claimed herein. As defined by Vendantham, hydroxyapatite chromatography is chromatography using ceramic hydroxyapatite as an absorbent. The present method does not remove impurities from a protein solution by absorption, such as by affinity chromatography, but by forming particles of the contaminants and then removing the particles.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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